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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,853	10/10/2001	Neville J. Anthony	20757Y	7109

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/05/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,853

Applicant(s)

ANTHONY ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-20, 28, 29 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 21-27, 30-32 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-11, 14 and 15
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1 and 3-37 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 13 is acknowledged.

The traversal is on the ground(s) that there would be no undue burden involved in the search and examination of Group V and Group I. This is not found persuasive because Group V is directed to combinations of compounds of Formula I and HIV infection/AIDS treatment agents which are classified based on the compounds, thus the additional active ingredient must be classified as well and thus creates further classes and subclasses.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 16-20, 28, 29 and 33-36 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25-27 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. The scope of composition and method of use claims are not adequately enabled solely based on HIV integrase provided in the specification. Claims 26, 27, 30 and 31 are the method of use of the compounds of the instant invention for use in the prevention of infection by HIV or delaying the onset of AIDS, which is not remotely enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-15, 21-27 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 3-15, 21-27 and 30-32 are vague and indefinite in that it is not known what is meant by the definition of Q^1 . There is no variable Q^1 in amended claim

1. b) Claims 1, 3-15, 21-27 and 30-32 are vague and indefinite in that it is not known what is meant by the proviso at the end of the claim. There are no Z^1 , Z^2 , Z^3 , X or Y variables in amended claim 1.

c) Claim 4 recites the limitation " $-(CH_2)_{0-3}C(=O)R^t$, $-N(R^a)R^t$ or $-(CH_2)_{1-3}R^{tu}$ " in the definition of the substituents on (5) within the definition of R^k . There is insufficient antecedent basis for this limitation in the claim.

d) Claim 4 recites the limitation "oxo" in the definition of the substituents on the rings of R^t . There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

e) Claim 7 recites the limitation " $-(\text{CH}_2)_{0-3}\text{C}(=\text{O})\text{R}^t$, $-\text{N}(\text{R}^a)\text{R}^t$ or $-(\text{CH}_2)_{1-3}\text{R}^{tu}$ " in the definition of the substituents on (5) within the definition of R^k . There is insufficient antecedent basis for this limitation in the claim.

f) Claim 7 is vague and indefinite in that it is not known what is meant by the moiety hexahydrooxazolo[3,4a]pyrazinyl in the definition of R^k paragraph (6).

g) Claim 7 recites the limitation "oxo" in the definition of the substituents on the rings of R^t . There is insufficient antecedent basis for this limitation in the claim.

h) Claims 8-10 are vague and indefinite in that there is no definition for the variable n .

i) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of Q^2 which is not stated in the form of a proper Markush grouping, i.e. the or which appears after (46).

j) Claims 8-10 are vague and indefinite in that it is not known what is meant by the moiety hexahydrooxazolo[3,4a]pyrazinyl in the definition of R^k paragraph (6).

k) Claims 9 and 10 recite the limitation " $-\text{N}(\text{R}^a)-\text{C}(=\text{O})-(\text{CH}_2)_{1-2}-\text{C}(=\text{O})-\text{N}(\text{R}^a)_2$ " in the definition of Q^2 . There is insufficient antecedent basis for this limitation in the claim.

l) Claims 9 and 10 are vague and indefinite in that it is not known what is meant by the moiety $-\text{N}(\text{R}^a)-\text{SO}_2\text{R}^k$ in the definition of Q^2 .

m) Claims 9 and 10 recite the limitation " $-\text{S}-\text{C}_{1-6}$ alkyl" in the definition of the substituents of paragraph (3) within the definition of R^k . There is insufficient antecedent basis for this limitation in the claim.

n) Claims 9 and 10 recite the limitation "-C₁₋₆ alkyl-N(R^a)₂" in the definition of the substituents of paragraph (3) within the definition of R^k. There is insufficient antecedent basis for this limitation in the claim.

o) Claims 11-13 are vague and indefinite in that it is not known what is meant by the moiety -N(R^a)- -SO₂R^k in the definition of Q².

p) Claim 21 recites the limitation "(2-oxo-2-pyrrolidin-1-ylethyl)" in the species 4th from the bottom of page 56. There is insufficient antecedent basis for this limitation in the claim.

q) Claim 21 recites the limitation "(pyrimidin-2-ylamino)" in the species at the bottom of page 58. There is insufficient antecedent basis for this limitation in the claim.

r) Claim 21 recites the limitation "(pyridin-2-ylmethyl)" in the species at the bottom of page 59. There is insufficient antecedent basis for this limitation in the claim.

s) Claim 21 recites the limitation "6-methyl" in the 3rd and 4th species on page 60. There is insufficient antecedent basis for this limitation in the claim.

t) Claim 21 recites the limitation "pyrimido[4,5,6-de]-1,6-naphthyridine" in the 4th species on page 62. There is insufficient antecedent basis for this limitation in the claim.

u) Claim 21 is vague and indefinite in that it is not known what is meant by the 8th species on page 62 which is missing a close parenthesis, i.e. (7- and an open parenthesis 4-fluorobenzyl).

v) Claim 21 recites the limitation "(dimethylaminosulfonyl)" in the 2nd to last species of claim 21. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

w) Claim 22 recites the limitation "(pyridin-2-ylmethyl)" in the 4th species on page 65. There is insufficient antecedent basis for this limitation in the claim.

x) Claim 22 recites the limitation "(2-oxo-2-pyrrolidin-1-ylethyl)" in the 5th species on page 65. There is insufficient antecedent basis for this limitation in the claim.

y) Claim 22 recites the limitation "6-methyl" in the 1st species on page 66. There is insufficient antecedent basis for this limitation in the claim.

z) Claim 22 recites the limitation "(pyrimidin-2-ylamino)" in the 2nd species on page 66. There is insufficient antecedent basis for this limitation in the claim.

aa) Claim 23 recites the limitation "pyrimido[4,5,6-de]-1,6-naphthyridine" in the 7th species on page 68. There is insufficient antecedent basis for this limitation in the claim.

ab) Claim 23 is vague and indefinite in that it is not known what is meant by the 4th species from the bottom of page 68 which is missing a close parenthesis, i.e. (7- and an open parenthesis 4-fluorobenzyl).

ac) Claim 23 recites the limitation "dimethylaminosulfonyl " in the 2nd species on page 71. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1624

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/218,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in 09/218,537 embrace the compounds, compositions and method of use of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/399,083. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in 10/399,083 embrace the compounds, compositions and method of use of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims of copending Application No. (Attorney Docket No. 20950Y). Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in (Attorney Docket No. 20950Y) embrace the compounds, compositions and method of use of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/398,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in 10/398,988 embrace the compounds, compositions and method of use of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/398,929. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in 10/398,929 embrace the compounds, compositions and method of use of the instant invention.

Art Unit: 1624

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/218,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I in 10/218,537 embrace the compounds, compositions and method of use of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 703-305-1880. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Brenda Coleman
Primary Examiner Art Unit 1624
November 3, 2003